IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

TANYA M. FREEMAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**DOCKET NO.: 2:17-cv-00231-JRG**
	)	
MERIT MEDICAL SYSTEMS, INC., CRYOLIFE, INC., HEMOSPHERE, INC., and HERBERT SLATERY, in his official capacity as Attorney General and Reporter of the State of Tennessee,	)	
	)	
Defendants.	)	

ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT FILED ON BEHALF OF CRYOLIFE, INC.

Defendant CryoLife, Inc. (hereafter "CryoLife") by and through its undersigned counsel, submits its Answer and Affirmative Defenses to Plaintiff's Complaint as follows:

PARTIES

1. Answering Paragraph 1, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of same is demanded.

2. Answering Paragraph 2, CryoLife admits upon information and belief that Defendant Merit Medical Systems, Inc. (hereafter "Merit Medical") is a Utah corporation, with its principal place of business at 1600 W. Merit Parkway, South Jordan, Utah, which manufactures and sells medical devices and products to hospitals and other health care providers throughout the United States and other countries. CryoLife is without sufficient knowledge or

information to form a belief as to the truthfulness of the remaining allegations contained therein, and strict proof of same is demanded.

3. Answering Paragraph 3, CryoLife denies that it is a Georgia corporation, but admits that its principal place of business is 1655 Roberts Blvd., NW, Kennesaw, Georgia. CryoLife asserts that it is a Florida corporation. CryoLife admits the remaining allegations contained therein.

4. Answering Paragraph 4, CryoLife denies the allegations as stated therein. CryoLife acquired Defendant Hemosphere, Inc. (hereafter "Hemosphere") in May 2012, and CryoLife and Hemosphere were merged on 1/1/15.

5. Answering Paragraph 5, CryoLife admits that Defendant Herbert Slatery (hereafter "Attorney General") is a citizen and resident of the State of Tennessee who serves as Attorney General and Reporter for the State of Tennessee, and may be served with process at 425 5th Ave. N., Suite 2, Nashville, Tennessee 37243. Further, CryoLife admits upon information and belief, that the Attorney General was not negligent or otherwise involved in the treatment of the Plaintiff. The remaining allegations set forth a legal conclusion that does not require a response from CryoLife.

6. Answering Paragraph 6, CryoLife denies the allegation as stated. Hemosphere was merged into CryoLife on 1/1/15, and thus Hemosphere is not in existence, and should be removed from the caption of the Complaint and all further pleadings. Merit Medical and CryoLife may be referred to as a "Defendants."

7. Answering Paragraph 7, CryoLife denies the allegations therein. CryoLife admits that it sold the HeRO graft product to Merit Medical on February 3, 2016, but CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness that CryoLife

manufactured the device. Furthermore, CryoLife denies that it sold the specific device that is the subject of this action to Johnson City Medical Center. CryoLife denies that any of its acts or omissions resulted in Plaintiff's injuries.

JURISDICTION AND VENUE

8. Answering Paragraph 8, CryoLife does not dispute jurisdiction of the United States District Court, Eastern District of Tennessee. CryoLife admits that it marketed its medical devices in Tennessee. However, CryoLife denies that it sold or shipped the specific device that was surgically implanted into the Plaintiff. The remaining allegation of Paragraph 9 is a legal conclusion that does not require a response from CryoLife.

9. Answering Paragraph 9, the allegation sets forth a legal conclusion that does not require a response from CryoLife.

10. Answering Paragraph 10, CryoLife denies that venue is proper. CryoLife asserts that this is a civil action between citizens of different states, the amount in controversy exceeds the sum of $75,000 (exclusive of interest and costs), and the Defendants, with the exception of the Attorney General, are not citizens of the State of Tennessee. The United States District Court for the Eastern District of Tennessee has original jurisdiction over this case pursuant to 28 U.S.C. § 1332 and removal is proper pursuant to 28 U.S.C. § 1441(a)-(b). Furthermore, CryoLife is without sufficient knowledge or information to form a belief as to whether the cause of action arose in Washington County.

FACTS

11. Answering Paragraph 11, CryoLife admits that it sold the HeRO graft product to Merit Medical in February 2016, and denies that it currently manufactures or sells the HeRO graft. During the time CryoLife manufactured the HeRO product line, CryoLife admits that at

least one of its purposes was to provide improved vascular access for patients needing hemodialysis. The remaining allegation is admitted as stated.

12. Answering Paragraph 12, CryoLife admits that the device is fully subcutaneous, but is without sufficient knowledge or information to form a belief as to how Merit Medical marketed the device and strict proof of same is demanded.

13. Answering Paragraph 13, CryoLife denies the allegations as contained therein.

14. Answering Paragraph 14, CryoLife denies that the HeRO graft is a relatively simple device. As to the remaining allegations, CryoLife is without sufficient knowledge or information to form a belief as to their truthfulness, and strict proof of the same is demanded.

15. Answering Paragraph 15, CryoLife denies that the allegation contained in the first sentence. CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the remaining allegations therein.

16. Answering Paragraph 16, CryoLife denies that Hemosphere first began manufacturing and selling the HeRO graft after March 7, 2013. CryoLife admits the HeRO graft is a § 510(K) device. CryoLife denies that it or Hemosphere affirmatively made a decision to forego premarket approval and asserts that the Food and Drug Administration decides the appropriate regulatory pathway for medical devices.

17. Answering Paragraph 17, CryoLife admits that it did not seek PMA approval. CryoLife asserts that the regulatory pathway for medical devices is made by the FDA. Furthermore, CryoLife asserts that the device had already been cleared under the 510(K) process when CryoLife acquired Hemosphere. CryoLife asserts that the FDA did not require CryoLife file a premarket approval application. CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the remaining allegation therein.

18. Answering Paragraph 18, CryoLife denies the legal conclusion therein. CryoLife asserts that Federal law preempts the product liability laws of the State of Tennessee in this action.

19. Answering Paragraph 19, CryoLife admits that it marketed the HeRO graft to general surgeons and vascular surgeons in the State of Tennessee when it owned the product line. CryoLife denies that it marketed the HeRO graft and other devices directly to consumer patients, including those living in Tennessee. CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of Merit Medical's advertisement and marketing endeavors.

20. Answering Paragraphs 20 through 23, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

21. Answering Paragraph 24, CryoLife is without sufficient knowledge or information relative to the discussion between Plaintiff and her physician; however CryoLife asserts that the instructions for use provided with each HeRO graft device included the risk that the HeRO graft was subject to catastrophic failure after implantation. CryoLife is without sufficient knowledge or information as to whether the public web site operated and maintained by Merit Medical identified such failure as a risk of the device. CryoLife denies that no warnings were provided to Dr. Evans that the HeRO graft was subject to catastrophic failure.

22. Answering Paragraph 25, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

23. Answering Paragraph 26, CryoLife denies the HeRO graft was unreasonably dangerous at the time that it left the control of Defendants. Furthermore, CryoLife denies that

the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it. CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the informational materials on the Merit Medical web site.

24. Answering Paragraph 27, the allegations contained therein are denied as stated. CryoLife asserts that the device as manufactured by CryoLife does not tear in half within weeks of implantation and does not cause extensive blood clots in the lungs of the recipients. Furthermore, CryoLife asserts that the device should not have been manufactured in any way other than the way it was.

25. Answering Paragraphs 28 and 29, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

26. Answering Paragraph 30, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein. However, CryoLife asserts that some physicians refer to a "thrill" generally as described by Plaintiff.

27. Answering Paragraphs 31 through 40, CryoLife is without sufficient knowledge or information to form a belief as to the truthfulness of the allegations contained therein, and strict proof of the same is demanded.

28. Answering Paragraph 41, the allegations therein are denied.

COUNT I – STRICT LIABILITY

29. Answering Paragraph 42, CryoLife reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

30. Answering Paragraph 43, CryoLife is without sufficient knowledge or information to form a belief as to whether it manufactured the device that is the subject of this action, but CryoLife denies that it presently manufactures the HeRO graft or the component parts.

31. Answering Paragraphs 44 through 50, the allegations as stated are denied.

COUNT II – FAILURE TO WARN

32. Answering Paragraph 51, CryoLife reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

33. Answering Paragraph 52, the allegations set forth a legal conclusion that CryoLife denies.

34. Answering Paragraph 53, the allegations contained therein are denied. CryoLife asserts that, at a minimum, the requisite warnings appeared in the instructions for use. Furthermore, a trained medical professional would have knowledge of the risks associated with the HeRo graft device.

35. Answering Paragraph 54, the allegation contained therein is denied.

COUNT III – NEGLIGENCE IN DESIGN OR MANUFACTURE

36. Answering Paragraph 55, CryoLife reasserts and incorporates by reference its responses herein to the allegations contained in Paragraphs 1 through 41 of the Complaint.

37. Answering Paragraph 56, the allegation sets forth a legal conclusion that does not require a response from CryoLife.

38. Answering Paragraphs 57 through 59, the allegations contained therein are denied.

COUNT IV – DECLARATORY JUDGMENT

39. Answering Paragraph 60, the allegation therein does not require a response from CryoLife; therefore, it is neither admitted nor denied.

40. Answering Paragraph 61, CryoLife admits that Plaintiff seeks a declaratory judgment that the provisions of Tenn. Code Ann. § 29-39-102 is unconstitutional, but CryoLife denies that Plaintiff is entitled to such relief.

41. Answering Paragraphs 62 through 66, the allegations as stated are legal conclusions that CryoLife denies.

RESERVATION OF RIGHT TO NAME OTHER PERSONS

42. Answering Paragraph 67, CryoLife is without sufficient knowledge or belief to form a belief as to the cause of the personal injuries suffered by Plaintiff, but denies it is liable for Plaintiff's injuries.

JURY DEMAND

43. Answering the Jury Demand, CryoLife also requests a trial by jury.

44. In answering the Prayer for Relief, CryoLife denies any and all liability to Plaintiffs.

45. All allegations in the complaint, not hereinabove expressly admitted or denied are now denied.

AFFIRMATIVE DEFENSES

Without conceding the burden of proof as to any issue, CryoLife asserts the following affirmative defenses in order to preserve its right to assert them at trial, to give Plaintiff notice of its intention to assert these defenses, and to avoid waiver of any defenses.

1. Plaintiff's Complaint and each and every purported cause of action therein fails to state a claim upon which relief can be granted, and the Complaint should therefore be dismissed in whole or in part.

2. Plaintiff's claims are or may be barred, in whole or in part, by the learned intermediary doctrine.

3. Plaintiff's claims are barred, in whole or in part, because there was no defect in the subject product at the time it left the manufacturer, seller and/or distributor's possession. The product was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was properly designed, manufactured, tested, inspected, and distributed with adequate and sufficient warnings at the time it left CryoLife's custody and control.

4. The injuries alleged by Plaintiff were or may have been caused, in whole or in part, by the misuse of the products, or because the use was contrary to the instructions provided with the products.

5. Plaintiff's claims are barred, in whole or in part, because at all times relevant the products and marketing of the products complied with all applicable laws and regulations to which the products were in any respect subject, including those of the U.S. Food and Drug Administration.

6. Plaintiff's claims are barred, in whole or in part, because the methods, standards, and techniques utilized in the preparation, design, manufacture, and marketing of the products were and are in conformity with the generally recognized state of medical knowledge, common and accepted procedure in the medical field, and state of the art at the time.

7. Plaintiff's claims are barred, in whole or in part, because the social utility and benefit of the products outweighed their risks, if any.

8. Plaintiff's claims are barred, in whole or in part, under Comment k of Section 402A of the Restatement (Second) of Torts (1965) and the Restatement (Third) of Torts: Product Liability §§ 2, 4, 6 and applicable case law.

9. Plaintiff's claims are barred, in whole or in part, by the principles set forth in Comment n to Section 388 of the Restatement (Second) of Torts (1965).

10. At all relevant times, the products at issue were accompanied by proper directions for use, pursuant to generally recognized prevailing standards in existence at the time. The warnings and instructions on the products were not the proximate cause of any injury alleged by Plaintiff.

11. Any alleged product defect or negligence was not the proximate cause of the injuries alleged by Plaintiff.

12. Plaintiff's claims may be barred, in whole or in part, because CryoLife acted reasonably and in good faith.

13. Plaintiff's claims may be barred, in whole or in part, because Plaintiff did not reasonably rely on any representation or omission by CryoLife.

14. Plaintiff's claims may be preempted, in whole or in part, by federal law, including but not limited to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394.

15. Plaintiff's claims may be barred, in whole or in part, because the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394 do not provide for a private right of action.

16. Any injuries or damages that Plaintiff may have sustained were the result of Plaintiff's knowing and voluntary assumption of the medical risks associated with the use of the

device described in the Complaint. Therefore, Plaintiff's damages are barred, in whole or in part, by the principles of assumption of risk and informed consent.

17. In the event that Plaintiff has sustained damages, as alleged in Plaintiff's Complaint, discovery or investigation may reveal that such injuries and/or damages were the result of the culpable conduct of Plaintiff, or another party or non-party. Should it be found, however, that CryoLife is liable to Plaintiff, any liability being specifically denied, then any damages are to be apportioned among the Plaintiff, co-Defendant and third-parties according to the degree of responsibility that each is found to have for the occurrence, in proportion to the entire measure of responsibility for the occurrence.

18. Plaintiff's claims are barred, in whole or in part, because the injuries alleged by Plaintiff may have been caused, in whole or in part, by pre-existing medical conditions unrelated to the allegations set forth in the Complaint and/or may have occurred by operation of nature or as a result of circumstances over which CryoLife had, and continues to have, no control.

19. Any damages that Plaintiff may have sustained were, or may have been, proximately caused by the negligence and fault of Plaintiff, and/or by the actions or inactions of third persons or parties or entities over whom CryoLife exercised no authority or control.

20. Plaintiff's damages, if any, were the result of intervening or superseding events, factors, occurrences, or conditions for which CryoLife is not liable.

21. Plaintiff's claims may be barred, in whole or in part, because Plaintiff failed to mitigate her alleged damages and failed to exercise reasonable care for her own health and safety.

22. Plaintiff's claims may be barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitation of awards, caps on recovery, and setoffs.

Specifically, CryoLife relies upon *Tenn. Code Ann. §29-39-102* to limit non-economic damages, if any.

JURY DEMAND AND PRAYER FOR RELIEF

WHEREFORE, having fully answered and defended, CryoLife requests a trial by jury of twelve jurors on all issues and causes of action so triable in this cause, and prays for judgment as follows:

A. That Plaintiff take nothing by the Complaint;

B. That judgment be entered for CryoLife and against Plaintiff on each and every claim set forth in Plaintiff's Complaint;

C. That CryoLife recover its fees, costs, and attorneys' fees incurred herein; and

D. Such other and further relief as the Court deems just and proper.

This 28th day of December, 2017.

CRYOLIFE, INC.

By: *s/ Jimmie C. Miller*

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CERTIFICATE OF SERVICE

I hereby certify that on the 28th day of December, 2017, a copy of the foregoing **Answer** was filed electronically using the Court's ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U. S. Mail. Parties may access this filing through the Court's electronic filing system.

s/Jimmie C. Miller
Jimmie C. Miller